

DRAFT LANGUAGE; new language in **bold**

Title 22, Chapter 401: GENERAL PROVISIONS

Section 1711-C, CONFIDENTIALITY OF HEALTH CARE INFORMATION

1. Definitions ...

**F. To the Maine Health Data Organization as required by and for use in accordance with Chapter 1683.**

Title 22, Chapter 1683: MAINE HEALTH DATA ORGANIZATION

Section 8702 DEFINITIONS:

**8702(4-B) Individually identifiable health information is information including demographic information about an individual reported to MHDO that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. For the purposes of this chapter it is synonymous with protected health information (PHI).**

**8702(9-B) Public health studies include all studies, investigations, and measures with a goal of improving health care, delivery and utilization of health care, cost of health care, and health care quality; and federally funded or state funded studies and projects for same.**

Section 8705-A ENFORCEMENT

(2) Rulemaking ...

**C. Intentionally or knowingly and without authorization using or disseminating individually identifiable health information on patients.**

**D. Intentionally or knowingly and without authorization using or disseminating information that identifies, or with respect to which there is a reasonable basis to believe the information can be used to identify health care practitioners performing abortions as defined in section 1596.**

Section 8707. PUBLIC ACCESS TO DATA ...

1. Public access; confidentiality. The board shall adopt rules making available to any person, upon request, information, except privileged medical information and confidential information, provided to the organization under this chapter as long as individual patients are not directly or

indirectly identified through a re-identification process. **[Individual patients may only be directly or indirectly identified, including through a linking or re-identification process, as provided in this chapter. Any individually identifiable health information shall be used only for the purposes for which the MHDO releases it.]** The board shall adopt rules to protect the identity of certain health care practitioners, as it determines appropriate, except that the identity of practitioners performing abortions as defined in section 1596 must be designated as confidential and must be protected. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

2. Notice and comment period. The rules must establish criteria for determining whether information is confidential clinical data, confidential financial data or privileged medical information and adopt procedures to give affected health care providers and payers notice and opportunity to comment in response to requests for information that may be considered confidential or privileged.

3. Public health studies. The rules may allow **[individual patients to be directly or indirectly identified, including through a linking or re-identification process]** only to the extent authorized in this subsection **[and Section 8707-A]**.

A. The board may approve access to **[individually]** identifying information for patients to the department and other researchers with established protocols **[including federally approved Internal Review Board oversight]** that have been approved by the board for safeguarding confidential or privileged information.

B. The rules must ensure that:

(1) Identifying information is used only to gain access to medical records and other medical information pertaining to public health **[studies]**;

(2) Medical information about any patient **[individually]** identified by name is not obtained without the consent of that patient except when the information sought pertains only to verification or comparison of health data and the board finds that confidentiality can be adequately protected without patient consent; **[or when the persons engaged in the public health study have access to individually identifiable health information on the patient as a health care provider, health plan, or public health authority as defined in 45 CFR 160.103 and 164.501, and privacy and security protections required under federal and state law are in place]**;

(3) Those persons conducting the research or investigation do not disclose medical information about any patient **[individually]** identified by name to any other person without that patient's consent;

(4) Those persons gaining access to medical information about an **[individually]** identified patient use that information to the minimum extent necessary to accomplish the purposes of the research for which approval was granted and **[for no other purpose];**

(5) The protocol for any research is designed to preserve the confidentiality of all health care information that can be associated with identified patients, to specify the manner in which contact is made with patients and to maintain public confidence in the protection of confidential information.

C. The board may not grant approval under this subsection if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation. ...

5. Rules for release, publication and use of data. The rules must govern the release, publication and use of analyses, reports or compilations derived from the health data made available by the organization.

#### **Section 8707-A. PAYER AND PROVIDER ACCESS TO PROTECTED HEALTH INFORMATION**

**1. Permitted Uses and Disclosures. The MHDO is permitted to use and disclose protected health information (PHI), without an individual's authorization, for the following purposes or situations:**

**A. Treatment, Payment, and Health Care Operations. The MHDO may disclose protected health information for the treatment activities of any health care provider, the payment activities of a covered entity and of any health care provider, or the health care operations of a covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if the covered entities have or had a relationship with the individual and the protected health information pertains to the relationship.**

- i. Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another.**
- ii. Payment encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care**

**delivered to an individual and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual.**

- iii. Health care operations are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.**
- 2. Minimum Necessary. The MHDO will develop policies and procedures that reasonably limit its disclosures of, and requests for, protected health information for payment and health care operations to the minimum necessary.**
- 3. For MHDO to release PHI under this section MHDO will provide an individual protection mechanism by which an individual may opt out from participation to prohibit the MHDO from disclosing the individuals health care information under this section. This opt out should be coordinated with the statewide health information exchange to the extent this can reasonably be done. The opt out mechanism shall meet the conditions of 22 MRS Section 1711-C (18)C-K to the extent applicable.**